

## § 423.466

## 42 CFR Ch. IV (10–1–12 Edition)

D plan learns that it has made an erroneous payment due to inaccurate or incomplete information on the satisfaction of the out-of-pocket threshold under § 423.104(d)(5)(iii), that plan is authorized to recover such costs directly from the Part D enrollee on whose behalf the costs were incurred. A Part D enrollee must reimburse the Part D plan for payment made for these costs.

(5) *Plan-to-plan liability.* In the process of coordinating benefits between Part D plans when a Part D plan from which a beneficiary has transferred has incorrectly made payment for covered prescription drug costs incurred after the effective date of the Part D enrollee's enrollment in the new Part D plan of record, the new Part D plan of record must make the reconciling payments based on amounts reported to it by CMS without regard to the Part D plan's own formulary or drug utilization review edits.

(6) *Use of other reconciliation processes.* In the process of coordinating benefits between the correct Part D plan of record and another entity providing prescription drug coverage when that entity has incorrectly paid as primary payer for a covered Part D drug on behalf of a Part D enrollee, the correct Part D plan of record must achieve timely reconciliation through working directly with the other entity that incorrectly paid as primary payer, unless CMS has established reconciliation processes for payment reconciliation, rather than requesting pharmacy claims reversal and re-adjudication.

(g) *Responsibility to account for other providers of prescription drug coverage when a retroactive claims adjustment creates an overpayment or underpayment.* When a Part D sponsor makes a retroactive claims adjustment, the sponsor has the responsibility to account for SPAPs and other entities providing prescription drug coverage in reconciling the claims adjustments that create overpayments or underpayments. In carrying out these reimbursements and recoveries, Part D sponsors must also account for payments made and for amounts being held for payment by other individuals or entities. Part D sponsors must have systems to track and report adjustment transactions and to support all of the following:

(1) Adjustments involving payments by other plans and programs providing prescription drug coverage have been made.

(2) Reimbursements for excess cost-sharing and premiums for low-income subsidy eligible individuals have been processed in accordance with the requirements in § 423.800(c).

(3) Recoveries of erroneous payments for enrollees as specified in § 423.464(f)(4) have been sought.

(h) *Reporting requirements.* A Part D sponsor must report credible new or changed supplemental prescription drug coverage information to the CMS Coordination of Benefits Contractor in accordance with the processes and timeframes specified by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20507, Apr. 15, 2008; 75 FR 19819, Apr. 15, 2010; 76 FR 21574, Apr. 15, 2011]

### § 423.466 Timeframes for coordination of benefits.

(a) *Retroactive claims adjustments, underpayment refunds, and overpayment recoveries.* Whenever a sponsor receives information that necessitates a retroactive claims adjustment, the sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the sponsor's receipt of complete information regarding claims adjustment.

(b) *Coordination of benefits.* Part D sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed 3 years from the date on which the prescription for a covered Part D drug was filled.

[75 FR 19819, Apr. 15, 2010]

## Subpart K—Application Procedures and Contracts with Part D plan sponsors

### § 423.500 Scope.

This subpart sets forth application procedures and contracts with Part D plans: application procedures and requirements; contract terms; procedures for termination of contracts; reporting by Part D plans. For purposes of this

subpart, Medicare Advantage (MA) organizations offering Part D plans follow the requirements of part 422 of this chapter for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements.

#### § 423.501 Definitions

For purposes of this subpart, the following definitions apply:

*Bona fide service fees* means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

*Business transaction* means any of the following kinds of transactions:

- (1) Sale, exchange, or lease of property.
- (2) Loan of money or extension of credit.
- (3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—
  - (i) Salaries paid to employees for services performed in the normal course of their employment; or
  - (ii) Health services furnished to the Part D plan sponsor's enrollees by pharmacies and other providers, by Part D plan sponsor staff, medical groups, or independent practice associations, or by any combination of those entities.

*Downstream entity* means any party that enters into a written arrangement, acceptable to CMS, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

*First tier entity* means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

*Party in interest* means the following:

(1) Any director, officer, partner, or employee responsible for management or administration of a Part D plan sponsor.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of a PDP sponsor organized as a nonprofit corporation, an incorporator or member of the corporation under applicable State corporation law.

(4) Any entity in which a person specified in paragraphs (1), (2), or (3) of this definition—

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with the Part D plan sponsor.

(6) Any spouse, child, or parent of an individual specified in paragraphs (1), (2), or (3) of this definition.

*Related entity* means any entity that is related to the PDP sponsor by common ownership or control and—

(1) Performs some of the Part D plan sponsor's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than \$2,500 during a contract period.

*Significant business transaction* means any business transaction or series of transactions of the kind specified in the above definition of business transaction that, during any fiscal year of the Part D plan sponsor, have a total value that exceeds \$25,000 or 5 percent of the PDP sponsor's total operating expenses, whichever is less.

[70 FR 4525, Jan. 28, 2005, as amended at 77 FR 22170, Apr. 12, 2012]